Section 5: 510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

APR 30 2013

Submitter Information	
Name	DePuy Orthopaedics, Inc.
Address	700 Orthopaedic Drive, Warsaw, IN 46582
Phone number	(574)
Fax number	(574) 371-4987
Establishment Registration Number	1818910
Name of contact person	Correne Ramy
Date prepared	February 27, 2013
Name of device	
Trade or proprietary name	DePuy M-Spec 36mm Femoral Heads
Common or usual name	Femoral heads
Classification name	Hip joint metal/polymer/metal, semi-constrained, porous-coated, uncemented prosthesis Hip joint metal/polymer, semi-constrained cemented prosthesis
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3358 and 21 CFR 888.3350
Product Code(s)	LPH, JDI
Legally marketed device(s) to which equivalence is claimed	36mm Articul/eze Femoral Heads (K980513, cleared April 14, 1998) DePuy M-Spec Femoral Heads (K060031, cleared January 31, 2006) DePuy LCS Femoral Hip Prosthesis (K880269, cleared May 6, 1988) DePuy ASphere M-Spec Femoral Heads (K082585, cleared December 4, 2008)
Reason for 510(k) submission	Line extension
Device description	The subject devices are a line extension to the existing range of Articul/Eze 36mm Femoral Heads and represent additional taper sizes and offsets to allow surgeons more flexibility in the choice of femoral hip stem. Specifically, the tapers include 12/14 Articul/Eze taper with +15.5mm offset, 11/13 S-ROM taper with -3mm, 0mm, +3mm, +6mm, +9mm and 12mm offsets, and 14/16 taper with 0mm, +3mm, +5mm, +8mm and +11mm offsets. The tapers are designed to mate with femoral hip stems which have matching neck taper sizes. The offsets vary to allow the surgeon flexibility in lateralization of the hip joint.
Intended use of the device	Total hip arthroplasty

Indications for use	Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. Porous-coated Pinnacle Acetabular Cups are indicated for cementless applications

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	DePuy M-Spec 36mm Femoral Heads	36mm Articul/eze Femoral Heads (K980513)	Modular M-Spec Femoral Heads (K060031)	ASphere M-Spec Femoral Heads (K082585)	LCS Femoral Hip Prosthesis (K880269)
Material	Cobalt-chromium-molybdenum	Cobalt-chromium-molybdenum	Cobalt-chromium-molybdenum	Cobalt-chromium-molybdenum	Cobalt-chromium-molybdenum
Head diameter	36mm	36mm	40, 44, 48mm	36, 40, 44mm	32mm
Offsets (taper style)	+15.5mm (12/14) -3, +0, +3, +6, +9, +12mm (11/13) +0, +3, +5, +8, +11mm (14/16)	-2, +1.5, +5, +8.5, +12mm (12/14)	-2, +1.5, +5, +8.5, +12, +15.5mm (12/14) -3, +0, +3, +6, +9, +12mm (11/13)	-2, +1.5, +5, +8.5, +12, +15.5mm (12/14) -3, +0, +3, +6, +9, +12mm (11/13)	+0, +5, 11mm (14/16)
Sterilization Method	Gamma radiation	Gamma radiation	Gamma radiation	Gamma radiation	Gamma radiation

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Dimensional analysis of femoral heads included in K980513, K060031, K880269, and K082585 compared to the subject devices was conducted to show substantial equivalence.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

No clinical testing was required to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.
% Ms. Correne Ramy
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46582

Letter dated: April 30, 2013

Re: K120599
Trade/Device Name: DePuy M-Spec 36mm Femoral Heads
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: February 25, 2013
Received: March 4, 2013

Dear Ms. Ramy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510 (k) Number (if known): K120599

Device Name: DePuy M-Spec 36mm Femoral Heads

Indications for Use:

Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

DOD—DIVISION SIGN-OFF

Division of Orthopedic Devices

510(k) Number: K120599

Elizabeth L. Frank -S